REMARKS

Claims 1-6 and 8-14 are pending. Claims 8-13 have been withdrawn. Claim 1 is in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

Claims 1-6 and 14 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 4,486,436 ("Sunshine et al."), U.S. Patent No. 4,943,565 ("Tencza et al."), Remington's Pharmaceutical Sciences p. 1837 ("Remington"), and U.S. Patent No. 6,602,520 ("Schroeder et al."). Applicants respectfully traverse these rejections, in view of the comments set forth below.

Claim 1 of the present invention is directed to a solid pharmaceutical dosage form that includes the noteworthy features of a caffeine, wherein the caffeine is in the form of uncoated ungranulated particles having an average particle size of about 70 to 600 microns, and wherein at least 86% of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm.

The Advisory Action dated April 14, 2010 states (i) that the references do not teach caffeine as granulated nor coated; (ii) the disintegration of caffeine or any other active can be adjusted by controlling the amount and type of distintegrating agent; and (iii) that Applicants are arguing the references separately when the rejection was made in combination.

Applicants have found that the claimed dissolution rate is achieved in large part by utilizing uncoated ungranulated caffeine, as recited in Claim 1. The prior art references cited in the Office Action do not disclose or suggest the dissolution rates achieved by the presently claimed invention, where at least 86% of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm has not been disclosed or suggested in the

prior art. In fact, Sunshine et al., Tencza et al., Remington's Pharmaceutical Sciences (p. 1837), and Schroeder et al. do not provide any examples where such rapid disintegration is achieved. As noted previously, the uncoated ungranulated caffeine utilized by Applicants helps achieve the higher and faster dissolution rate recited in Claim 1.

Regarding point (iii), Applicants respectfully submit that arguments have been presented over the proposed combination of Sunshine et al., Tencza et al., Remington's Pharmaceutical Sciences (p. 1837), and Schroeder et al. Applicants respectfully direct the Examiner's attention to page 3, of Applicants' response dated March 19, 2010. Applicants explained that the proposed combination would result in a solid pharmaceutical dosage form that includes caffeine, wherein at least 75% of the dosage form, dissolves in less than 45 minutes. In contrast, the pharmaceutical dosage form recited in Claim 1 includes uncoated ungranulated caffeine, wherein at least 86% of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm, as set forth in Claim 1. Clearly caffeine dissolution at a rate of at least 86% dissolution within 5 minutes is far superior to a dissolution rate of at least 75% of the dosage form in less than 45 minutes. Applicants note that the improved rate of dissolution is due to the use of uncoated ungranulated caffeine. As such, Claim 1 is patentable over Sunshine et al., Tencza et al., Remington, and Schroeder et al., whether considered separately or in combination.

A dissolution rate where at least 75% of the caffeine-acetaminophen tablet dissolves in under 45 minutes is not the same as a dissolution rate of at least 86% dissolution within 5 minutes. The amount of dissolution and the time constraint in which it is achieved are much more rapid utilizing the claimed invention as recited in Claim 1. The superior results are in large part due to utilizing uncoated ungranulated caffeine.

If the Examiner believes otherwise, then Applicants respectfully request that the Examiner clarify her position and explain why she believes that a dissolution rate of at least 86% dissolution within 5 minutes is not superior to or better than a dissolution rate of at least 75% of the dosage form in less than 45 minutes.

Claims 2-6 and 14 directly or indirectly depend from Claim 1. For at least the same reasons discussed above for Claim 1, Claims 2-6 and 14 are patentable over Sunshine et al., Tencza et al., Remington, and Schroeder et al., taken separately or in combination.

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our office by telephone at (732) 524-1767. All correspondence should continue to be directed to our below listed address.

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